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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

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| **Deena Patel Aeron**, **Virgil Jose**, **Jeanne Jose**, **Fernando Velloso**, and **Franne Einberg**, on behalf of themselves and all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>**23andMe, Inc.,**<br><br>Defendant. | Case No. 13-cv-2847 JAH (JMA)<br><br>**First Amended Complaint** |

Plaintiffs Deena Patel Aeron, Virgil Jose, Jeanne Jose, Fernando Velloso, and Franne Einberg (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, allege as follows upon information and belief:

## Introduction

1. Defendant 23andMe, Inc. ("Defendant") advertised and marketed its Personal Genome Service ("PGS"or the "Device") as a diagnostic medical service beginning in 2008, offering health reports on more than 240 conditions and genetic

traits, drug sensitivity and response, carrier status for genetic conditions and deformities, among other things, without having either prior approval from the FDA or analytical or clinical validation for its claims. Defendant intended to collect genetic samples in order to create a database of genetic information, which it would then sell to third parties such as pharmaceutical and insurance companies.

2. Defendant knew for several years predating the filing of this action that it was on borrowed time: it knew it had no regulatory approval for its marketing, as required by federal law; knew that it could not support its claims with clinical or analytical evidence; and knew that the FDA would at some point order it to stop. On November 22, 2013, the FDA sent a warning letter to 23andMe, ordering the company to discontinue immediately all marketing of the Device.

3. Defendant deliberately ignored its obligations under federal and state law and engaged in a calculated campaign of delay and obfuscation in its dealings with FDA regulators. At the same time, Defendant increased its marketing efforts and slashed the price of its services from $399 to $299 and then to $99, in a desperate attempt to gather as much genetic material as possible before it was shut down.

4. Plaintiffs and members of the class paid hundreds of dollars and voluntarily provided Defendant with a sample of their genetic material in the form of saliva, using a kit furnished by Defendant complete with a prepaid shipping label and packaging to send the sample directly from the consumer to a third party laboratory.

## Parties

5. All named Plaintiffs are natural persons who purchased the PGS Device directly from Defendant. Plaintiffs are each residents of California.

6. Defendant 23andMe, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business in Mountain View, California. It offers the Personal Genome Service for sale worldwide through its website.

## Jurisdiction and Venue

7. This Court has diversity jurisdiction over the action pursuant to 28 U.S.C. § 1332(d) as at least one member of the plaintiff class is a citizen of a state different from the Defendant and the amount in controversy exceeds the jurisdictional minimum.

8. Venue is proper in this District because a substantial part of the events or omissions giving rise to the claims occurred here and Defendant regularly does business here.

## Facts

9. 23andMe was founded in 2006 by Linda Avey and Anne Wojcicki, with the stated intention of creating "a new research model" for genetics. According to the company's website in June, 2007, Ms. Avey's "primary interest is the acceleration of personalized medicine, using genetic profiles to target the right drug to the right person at the correct dose." Ms. Wojcicki pledged that "23andMe will create a common, standardized resource that has the potential to accelerate drug discovery and bring personalized medicine to the public."

10. As the company's history unfolded, it became clear that this stated dual purpose — to create a consumer diagnostic product and a database of genetic information — was in reality a carefully constructed fiction. As 23andMe board member Patrick Chung revealed in an interview published in *FastCompany* magazine on October 14, 2013, "Once you have the data, [the company] does actually become the Google of personalized health care." In the same interview,

Mr. Chung stated that the company has been in discussions with government-run single-payer health systems around the world to sell access to Defendant's database of genetic information. The company's newly-hired president, Andy Page, said that the goal of customer growth was to create a massive database in order to attract "research partnerships where we get paid well for [access to the data]."

**A. The PGS Device**

11. Defendant's Personal Genome Service is a direct-to-consumer genetic test of a customer's DNA to identify single nucleotide polymorphisms and patterns of such polymorphisms in order to correlate these variations with susceptibility to various diseases. Defendant also claims that the Device will show a particular person's response to certain prescription drugs. The PGS is purchased only on Defendant's website and was originally offered at $399 when sales began in early 2009. Defendant then dropped the price to $299 and then further to $99 in late 2012.

12. Because of its claimed usefulness in identifying diseases and drug response, 23andMe's PGS is a Class III device requiring premarket approval from the federal Food and Drug Administration. Federal law requires any device that "is purported or represented to be ... for a use which is of substantial importance in preventing impairment of human health" is subject to premarket approval by the FDA in order to ensure its safety and effectiveness. 21 USC § 360c(a)(C)(ii). That is, before a Class III device may even be offered for sale, the seller must prove that the device is safe and effective based on clinical data. 21 USC § 360e(c)(1)(A). Alternatively, a seller may propose a development protocol to the FDA, setting out specific tests and studies to be performed which will show both safety and efficacy, and if the protocol is both accepted by the FDA and completed by the

seller, the device will be considered to be approved for marketing. 21 USC § 360e(f).

13. Beginning at least as early as 2009, Defendant marketed the Device even though it had no premarket approval from the FDA. Defendant represented in public statements on its website, as well as in print, audio, and video advertising that the PGS would be of substantial importance in preventing impairment of human health. As late as November 26, 2013, Defendant made the following claims on its website, which are typical of claims it made elsewhere:

- "Learn hundreds of things about your health. Using your DNA information, 23andMe helps you know more about your health so you can take an active role in managing it. With reports on over 240+ health conditions and traits, here are a few of the things you'll learn about you."
- "Plan for the future. Find out if your children are at risk for inherited conditions, so you can plan for the health of your family."
- "Living well starts with knowing your DNA."
- "Health tools - Document your family health history, track inherited conditions, and share the knowledge."
- "Drug response - Arm your doctor with information on how you might respond to certain medications."
- "Below are a few examples [diabetes, arthritis, coronary heart disease, breast cancer, plavix, lactose intolerance] where we can help you learn more. And when you know more, you can make better lifestyle choices, look out for common conditions and take steps toward mitigating serious diseases."

14. Defendant markets and advertises specific examples of diseases and conditions for which the PGS can aid the consumer. Further, Defendant claims, "Get personalized recommendations. Based on your DNA, we'll provide specific

health recommendations for you." Defendant offers information on a consumer's risk regarding such serious diseases as diabetes, coronary heart disease, and breast cancer.

15. Defendant describes the PGS service further:

> "23andMe is a DNA analysis service providing information and tools for individuals to learn about and explore their DNA. We use the Illumina HumanOmniExpress-24 format chip...Our chip consists of a fully custom panel of probes for detective single nucleotide polymorphisms (SNPs) selected by our researchers. The selection was made to maximize the number of actionable health and ancestry features available to customers as well as offer flexibility for future research."

16. Defendants representations above are material to reasonable consumers.

17. Without clinical data, Defendant continues to make health and efficacy claims about the PGS. Without such claims, consumers would lack incentive to purchase the product. Thus, Defendant has benefitted, and continues to benefit, from its misleading and unfair advertising and marketing.

18. If the data is unknown or cannot be produced by researchers, the marketing claims are hollow and misleading, created without backing and with the aim of drawing customers to purchase the product.

19. In a January 9, 2013 letter, Defendant stated to FDA that it was "completing the additional analytical and clinical validations for the tests that have been submitted" and "planning extensive labeling studies that will take several months to complete." Thus, a full 5 years after the commencement of marketing the PGS to consumers, Defendant cannot support its marketing claims with scientific validation. In the absence of validation, 5 years of marketing claims were unfair, deceptive, and misleading to the consumers who trusted Defendant with potentially life-altering health matters.

20. Defendant also publishes "research" based on the test results it complies from individual consumers paying to have the PGS test administered, falsely claiming the results provide meaningful statistical data and useful scientific results.

21. In committing the wrongful acts alleged herein, Defendant, in concert with its subsidiaries, affiliates, and/or other related entities and their respective employees, planned, participated in and furthered a common scheme to induce members of the public to purchase the PGS by means of misleading, deceptive and unfair representations, and that Defendant participated in the making of such representations in that it disseminated those misrepresentations and/or caused them to be disseminated.

22. Even though Defendant made multiple claims about the Device's ability to help consumers avoid diseases and get customized drug treatment, 23andMe never obtained premarket approval for the PGS.

23. As the FDA wrote in its Warning Letter dated November 22, 2013, "more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS."

24. Failure to obtain premarket approval for a Class III device means that any sale of the device, or even an attempt to sell the device by advertising or marketing the product, is a federal crime. 21 USC § 333(a).

25. On May 21, 2013, the FDA wrote to Defendant to remind the company (as it had by similar letter on March 12, 2013) that it considered its regulatory submissions withdrawn. The FDA once again pointed out that 23andMe had failed to provide information sufficient to support a determination that the PGS device should be cleared for marketing under the "substantial equivalency" test. As the FDA later wrote, despite "many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for

its intended uses, which have expanded from the uses that the firm identified in its submissions." Letter of November 22, 2013 ("Warning Letter").

**B. Defendant Ignores the FDA and Increases Its Marketing**

26. Rather than respond to the FDA's repeated concerns, Defendant placed vast resources on marketing instead of science, broadening its marketing claims instead of narrowing them as required by federal law.

27. In June, 2013, Andy Page was hired as President of the company. Mr. Page had formerly led Gilt Groupe, an internet fashion company that offers "instant insider access to today's top designer labels" and has no background in science, biology, computational genomics, or medicine. Mr. Page in turn hired Neil Rothstein, formerly with streaming media provider Netflix, to be the head of marketing for Defendant.

28. Defendant then commissioned a series of focus groups and soon discovered that many people in the target audience were reluctant to share their genetic data, repeatedly expressing concerns about privacy and future discrimination based on genetic typology.

29. In August, 2013, Defendant launched a multi-million dollar advertising campaign, including for the first time in the company's history a series of television commercials. At the same time, however, Defendant refused to communicate in any way with the FDA after May 2013. Defendant's silence towards the federal regulators stood in glaring contrast to its loud proclamations in the marketplace. None of these marketing claims, however, were supported by clinical or analytical evidence.

**C. Plaintiff-Specific Allegations of Fact**

30. **Deena Patel Aeron**. Plaintiff Deena Patel Aeron is a resident of San Diego County, a wife and a mother. Both her parents and her husband's parents

immigrated to the United States from India. In both families, by tradition and culture, health issues are not discussed openly, if at all. Older generations seldom speak of diseases or health history of family members and chronic illness or disability can cause a person to be socially shunned, even by members of the same nuclear family.

31. As the mother of two small children, Plaintiff Aeron wanted to inform herself of any hereditary health issues she may have passed on genetically to her children, and purchased two of Defendant's PGS Device for herself and her mother, paying a total of $433.99 on May 4, 2011. She submitted a biological sample and reviewed the results sent by Defendant via email.

32. The health results supplied by Defendant included claims about Plaintiff Aeron's genetic predisposition to certain diseases and conditions, and promised additional updates based on "scientific discoveries" in the future.

33. Based on this information, Plaintiff Aeron made significant lifestyle changes, undertook increased medical testing and monitoring, and became more concerned about future health issues.

34. Had Plaintiff Aeron known that 23andMe's Personal Genome Service was unsupported by clinical or analytical validation, she would not have purchased the Device. Additionally, she would not have changed her lifestyle nor increased the frequency of medical testing and monitoring for herself and her children.

35. **Virgil and Jeanne Jose**. Plaintiffs Virgil and Jeanne Jose are residents of San Bernardino County, and are a married couple in their 70s. Mr. and Mrs. Jose paid Defendant 23andMe for two PGS devices in September 2013, and received back generic, boilerplate results. For example, Plaintiff Virgil Jose was described as being 31.6% of Italian 97.4% European ancestry. Defendant also warned Plaintiff Virgil Jose that he had a slightly elevated risk for atrial fibrillation and prostate cancer — hardly radical claims to make for a 76 year old man.

36. Prior to the FDA's warning letter, Plaintiff Virgil Jose contacted Defendant and asked for a refund, believing the PGS Device to be an unethical attempt to collect DNA data based on false claims and promises. He received a form response that did not address his specific concerns and no refund from Defendant.

37. Had either Plaintiff Virgil Jose or Plaintiff Jeanne Jose known that the marketing claims made by 23andMe were unsupported by clinical data, they would not have purchased the Device. Had either known that the Device was marketed without FDA approval, they would not have purchased the Device.

38. **Fernando Velloso**. Plaintiff Fernando Velloso is a husband and father and resides with his family in Los Angeles County. He purchased Defendant's PGS Device in late 2009, spending $399 each for three Devices for himself, his wife, and his young daughter. The health results supplied by Defendant included claims about Plaintiff Velloso's genetic predisposition to certain diseases and conditions, and promised additional updates based on "scientific discoveries" in the future.

39. Based on this information, Plaintiff Velloso, his wife, and their minor daughter made significant lifestyle changes, avoided specific foods, and took other steps as recommended by Defendant's results.

40. Had Plaintiff Velloso known that 23andMe's Personal Genome Service was unsupported by clinical or analytical validation, he would not have purchased the Device for himself and his family. Additionally, he would not have changed his lifestyle nor his diet, nor would he have supplied his own or his family's genetic material for sequencing and retention by Defendant.

41. **Franne Einberg**. Plaintiff Einberg is a woman in her 60s who resides in Los Angeles County. She purchased Defendant's PGS Device in August 2013, after viewing a segment on NBC's The Today Show about the Device.

42. She received her results in October and was shocked at how poorly the results corresponded with her own life. For example, Defendant claimed that Plaintiff Einberg mostly likely had straight blond hair and blue eyes, when she actually has very curly brown hair and brown eyes. She emailed Defendant's customer support and asked them to explain the discrepancies, hoping to gain additional insight into her overall genetic profile.

43. Defendant replied that the "SNP reported by 23andMe accounts for less than 10% of the variation in hair curl seen in European populations," along with other qualifications which were not present in Defendant's marketing materials. Despite the broad marketing claims, by Defendant's own admission its testing was useless even for trivial matters such as hair curl and eye color. Defendant's email also stated that the Device "has not been approved by the FDA for diagnostic testing" — yet no mention of the lack of FDA approval was made by Defendant prior to charging Plaintiff Einberg money for the Device.

44. Defendant also sent Plaintiff Einberg test results regarding her health risks and failed to find a single genetic marker for any elevated cancer risk. This directly conflicted with Plaintiff Einberg's family health history. More than half of the members of Plaintiff Einberg's family on both her mother's side and father's side for at least two generations has had fatal cancer diagnoses. That Defendant did not even mention cancer as a possible risk suggested to Plaintiff Einberg that the PGS Device was deeply flawed, particularly when coupled with the obviously oversold claims about hair curl and eye color.

45. Based on these results and others, together with Defendant's explanations, Plaintiff Eiberg believes that she has been defrauded by 23andMe. Had she known that the PGS Device lacked FDA approval and was unsupported by clinical or analytical validation, she would not have purchased the Device nor would she have supplied her genetic material for sequencing and retention by Defendant.

**D. Class Action Allegations**

46. Plaintiffs bring this class action lawsuit on behalf of themselves and all other similarly situated. Plaintiffs seek certification of the following class of persons:

> All persons in the United States who purchased a 23andMe Personal Genome Service within the class period.

47. Collectively, these persons will be referred to as "Class members." Plaintiff represents, and is a member of, the Class. Excluded from the Class are Defendant and any entities in which Defendant or their subsidiaries or affiliates have a controlling interest, Defendant's officers, agents and employees, the judicial officer to whom this action is assigned and any member of the Court's staff and immediate families, as well as claims for personal injury, wrongful death, and emotional distress.

48. Plaintiffs do not know the exact number of members in the Class, but based upon Defendant's public statements regarding its business, Plaintiffs reasonably believe that Class members number approximately 500,000 persons. As such, Class members are so numerous that joinder of all members is impractical.

49. Well-defined, common legal and factual questions affect all Class members. These common questions predominate over questions that might affect individual Class members. Common questions include but are not limited to whether Defendant's advertising, in any medium, was unfair, deceptive, untrue, or misleading; whether Defendant sold the PGS Device with knowledge of its ineffective, incomplete, unreliable, or misleading results; whether Defendant's terms of service were fairly and adequately disclosed to Class members; whether Defendant's terms of service include unconscionable or illusory terms, or both; and

whether Defendant obtained appropriate and timely premarket approval from the FDA to place its PGS Device into the stream of commerce, among others.

50. Plaintiffs will fairly and adequately represent and protect the interests of all Class members and Plaintiffs have no interests which are antagonistic to those of Class members. Plaintiffs have retained counsel with experience prosecuting consumer class action and complex litigation claims.

51. A class action is a class action is superior to all other available methods for the fair and efficient adjudication of the controversy for the following reasons:

a. It is economically impractical for members of the Class to prosecute individual actions;

b. The Class is readily definable; and

c. Prosecution as a class action will eliminate the possibility of repetitious litigation.

52. A class action will cause an orderly and expeditious administration of the claims of the Class. Economies of time, effort, and expense will be fostered and uniformity of decisions will be ensured.

53. Class wide relief is essential to compel Defendant to comply with California and federal law. The interest of Class members in individually controlling the prosecution of separate claims against Defendant is small because the damages in an individual action are small, amounting to a refund of less than one hundred dollars per customer. Management of the claims here is likely to present significantly fewer difficulties than are presented in many class claims because the PGS Device at issue is identical from customer to customer and Defendant's failure to obtain FDA premarket approval for the Device is identical for each purchaser.

54. Defendant has acted on grounds generally applicable to the Class, thereby making final injunctive relief and corresponding declaratory relief with the

respect to the Class as a whole appropriate. Moreover, the violations complained of herein are substantially likely to continue in the future if an injunction is not entered.

**First Cause of Action**

Unfair and Fraudulent Practices

55. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

56. This cause of action is brought on behalf of Plaintiff and members of the general public pursuant to the "unfair" and "fraudulent" prongs of California Business & Professions Code §§ 17200 *et seq*. ("UCL"), which provide that "unfair competition shall mean and include any unlawful, unfair or deceptive business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter I (commencing with Section 17500) as Part 3 of Division 7 of the Business and Professions Code."

57. As alleged above, Plaintiffs have standing to pursue this claim because each Plaintiff has suffered injury in fact and has lost money or property as a result of Defendant's actions as set forth herein. Specifically, prior to the filing of this action, Plaintiffs purchased the PGS Device that unfairly, unlawfully, deceptively, and misleadingly represented it would allow buyers to "[l]earn hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[g]et personalized recommendations," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance.

58. In fact, the PGS Device does none of those things and the results it provides are not supported by any scientific evidence.

59. In its marketing and advertising, Defendant makes false and misleading statements regarding the uses and benefits of the PGS.

60. The misrepresentations by Defendant are material facts and constitute an unfair and fraudulent business practice within the meaning of the UCL.

61. Defendant's business practices, as alleged herein, are unfair and fraudulent because: (1) the injury to the consumer is substantial; (2) the injury is not outweighed by any countervailing benefits to consumers or competition; and (3) consumers could not reasonably have avoided the information because Defendant intentionally mislead the consuming public by means of the claims made with respect to the PGS as set forth herein.

62. Defendant's business practices as alleged herein are fraudulent because they are likely to deceive customers into believing that the PGS Device has uses and benefits that it does not have.

63. In addition, Defendant's use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise which are not as represented in any manner constitutes unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of the UCL.

64. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct of unfair competition because Defendant is marketing and selling the PGS in a manner likely to deceive the public.

65. Plaintiffs and the putative class members were misled into purchasing the PGS Device by Defendant's deceptive conduct as alleged above. Plaintiffs and other putative class members were misled because the misrepresentations and omissions were uniform and material.

66. Pursuant to Bus. & Prof. § 17203, Plaintiffs and the Class members seek an order of this Court enjoining Defendant from continuing to engage, use, or employ its unfair and fraudulent practice of advertising the sale and use of the PGS products. Likewise, Plaintiffs and the Class members seek an order requiring Defendant to cease claiming the PGS can allow consumers to "[l]earn hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[g]et personalized recommendations," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance.

67. Plaintiffs also request an order awarding Plaintiffs and the Class restitution of the money wrongfully acquired by Defendant by means of its false and misleading representations.

68. Plaintiffs have suffered injury in fact and have lost money as a result of Defendant's false and misleading representations.

**Second Cause of Action**

Unlawful Business Practices

69. Plaintiff re-alleges and incorporates by reference the allegations set forth in this Class Action Complaint.

70. This cause of action is brought on behalf of Plaintiffs and members of the general public pursuant to the "unlawful" prong of the UCL, which provides that "unfair competition shall mean and include any unlawful, unfair or deceptive business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter I (commencing with Section 17500) as Part 3 of Division 7 of the Business and Professions Code."

71. As alleged above, Plaintiffs have standing to pursue this claim as Plaintiffs have suffered injury in fact and have lost money or property as a result of Defendant's common actions. Specifically, prior to the filing of this action, Plaintiffs each purchased the PGS Device that unfairly, unlawfully, deceptively, and misleadingly represented it would allow buyers to "[l]earn hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[g]et personalized recommendations," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance. In fact, the PGS does none of those things and the results it provides are not supported by any scientific evidence.

72. In its marketing and advertising, Defendant makes false and misleading statements regarding material facts — namely, the uses and benefits of the PGS Device — which are unlawful business practices.

73. Defendant's business practices, as alleged herein, are also unlawful because: (1) they violate the Federal Food Drug and Cosmetic Act (21 U.S.C. §§ 301, *et seq*.) and the California Sherman Law (Health & Safety Code § 110100, *et seq*.), (2) they violate sections 1770(a)(5), 1770(a)(7), 1770(a)(9) and 1770(a)(16) of the Consumer Legal Remedies Act, Civil Code § 1750, *et seq*.; and (3) they violate Business & Professions Code § 17500.

74. Pursuant to Business & Professions Code § 17203, Plaintiffs and Class members seek an order of this Court enjoining Defendant from continuing to engage, use, or employ its unfair and fraudulent practice of advertising the sale and use of the Products. Likewise, Plaintiffs and Class members seek an order requiring Defendant to cease claiming the PGS can allow consumers to "[l]earn

hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[g]et personalized recommendations," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance.

75. Plaintiffs also request an order awarding Plaintiffs and Class members restitution of the money wrongfully acquired by Defendant by means of its illegal business practices.

76. Plaintiffs have each suffered an injury in fact and have lost money or property as a result of Defendant's illegal business practices.

**Third Cause of Action**

False and Misleading Advertising

77. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

78. This cause of action is brought pursuant to Business & Professions Code §§ 17500, *et seq*., which provides that it is unlawful for any person or corporation, or any employee thereof "with intent directly or indirectly to dispose of real or personal property . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property . . . or concerning any circumstance or matter of fact connected with the proposed performance or

disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

79. In its advertising and marketing of the PGS Device, Defendant makes false and misleading statements that the PGS can allow consumers to "[l]earn hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[g]et personalized recommendations," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance.

80. Plaintiffs purchased the PGS that unfairly, unlawfully, deceptively, and misleadingly represented it can allow consumers to "[l]earn hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[g]et personalized recommendations," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance. In fact, the PGS does none of those things and the results it provides are not supported by any scientific evidence.

81. Defendant engaged in the deceptive conduct alleged above, which included deceptive and untrue representations regarding the PGS product, made to induce the public to purchase the product and supply Defendant with a sample of each customer's genetic material for sequencing.

82. In its marketing and advertising, Defendant makes knowingly false and misleading statements regarding the ingredients, characteristics, uses and benefits of the Products.

83. Defendant is aware that the claims that it makes about the Products are false and misleading.

84. In addition, Defendant's use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods, devices, or merchandise which are not as represented in any manner constitutes unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of Business & Professions Code §§ 17500, *et seq*.

85. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

86. Plaintiffs and Class members were misled into purchasing the Products by Defendant's deceptive conduct as alleged above.

87. Plaintiffs and Class members were misled and the misrepresentations and omissions were uniform and material.

88. Pursuant to Business & Professions Code §§ 17203 and 17535, Plaintiffs and Class members seek an order of this Court enjoining Defendant from continuing to engage, use, or employ its practice of advertising the sale and use of the Product claiming it can allow consumers to "[l]earn hundreds of things about your health," "[p]lan for the future," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[d]ocument your family health history, track inherited conditions, and share the knowledge," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about the buyer's susceptibility to conditions like diabetes, arthritis, coronary heart disease, breast cancer, plavix, and lactose intolerance. Plaintiffs also requests an order awarding Plaintiffs and Class

members restitution of the money wrongfully acquired by Defendant by means of responsibility attached to Defendant's false and misleading representations.

89. Plaintiffs have each suffered injury in fact and have lost money as a result of Defendant's false representations.

**Fourth Cause of Action**

Breach of Warranty

90. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

91. Defendant developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the PGS Device, in the course of same, directly advertised or marketed the PGS Device as described above to the FDA and consumers, including Plaintiffs.

92. Defendant impliedly warranted its PGS Device to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

93. Defendant breached its implied warranties for the PGS Device sold to Plaintiffs and Class members because this product was not fit for its common, ordinary, and intended use.

94. As a direct, foreseeable and proximate result of Defendant's breaches of implied warranties, Plaintiffs and Class members suffered injury and economic losses when Plaintiffs and Class members purchased the PGS Device in reasonable reliance upon the implied warranties.

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**Fifth Cause of Action**

Unjust Enrichment

95. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

96. Plaintiffs and Class members bring this claim in the alternative to their Breach of Warranty claims.

97. Defendant knowingly retained a benefit in the form of substantial revenues and payments from Plaintiffs and Class members for the PGS Device at the expense of Plaintiffs and Class members from Defendant's conduct and misrepresentations regarding the reliability and accuracy of the PGS Device.

98. Defendant knowingly retained a benefit in the form of personal DNA sequencing and genomic information when the PGS Device containing a biological sample for the person's saliva was sent to Defendant's agent, non-party National Genetics Institute ("NGI"), as directed by Defendant. NGI then sequenced the biological sample and sent the genetic sequencing data to Defendant.

99. Plaintiffs' and Class members' detriment and Defendant's enrichment are traceable to, and resulted directly and proximately from, the conduct challenged in this Complaint. Had Defendant not illegally marketed its PGS Device, Plaintiffs and Class members would not have paid money nor given biological samples to Defendant.

100. It would be inequitable for Defendant to retain the benefits it received and continues to receive from Plaintiffs and Class members without a payment to Plaintiffs and Class members.

101. Plaintiffs and Class members may have no adequate other remedy at law.

102. Plaintiffs and the Class seek disgorgement of and/or a constructive trust on all of the inequitable payments and profits Defendant retained from Plaintiffs and Class members.

**Sixth Cause of Action**

Deceit by Concealment

103. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

104. Defendant willfully deceived Plaintiffs and Class members by concealing from them the true facts concerning the PGS Device which Defendant was obligated to disclose. As set forth above, Defendant knew in advance of Plaintiffs' and Class members' use of the PGS Device, the lack of scientific validity associated with the PGS, and its own failure to obtain premarket approval for the Device.

105. Defendant concealed and failed to disclose the foregoing facts to Plaintiffs, Class members, and the general public.

106. As a result of the deceit by concealment by Defendant, Plaintiffs and Class members suffered the injuries and damages set forth above, including the loss of money and submission of their personal genetic information.

**Seventh Cause of Action**

Negligent Misrepresentation

107. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

108. Defendant made false misrepresentations, as previously set forth herein, to Plaintiff, Class members, and the general public, including without limitation, the misrepresentation that the PGS Device was effective, scientifically valid, and could provide consumers with meaningful health-related information.

109. Defendant made such representations without reasonable grounds for believing them to be true. These representations were made directly by Defendant and its authorized agents on the PGS Device packaging and in publications and

other written materials directed to the public, with the intention of inducing reliance and the purchase and use of the Device.

110. The foregoing representations by Defendant were in fact false. The PGS Device is not effective, not supported by analytical or clinical data, and cannot provide consumers with personalized, meaningful health-related information.

111. The foregoing representations by Defendant were made with the intention of inducing reliance on those misrepresentations so that Plaintiffs and Class members would purchase the PGS Device and supply a biological sample for genetic sequencing. Defendant also intended and induced Plaintiffs and Class members to supply additional information about lifestyle, personal habits, health history, and similar private information. Defendant uses this information together with the genetic sequencing data to create a research database which it markets to insurance companies, researchers, pharmaceutical companies, national health systems, and other business, charging money which Defendant retains for its own use.

112. In reliance on the above misrepresentations by Defendant, Plaintiffs and Class members were induced to purchase the PGS Device and submit a biological sample. If Plaintiffs had known of the true facts and the facts concealed by Defendant, Plaintiffs would not have purchased the PGS nor supplied biological samples.

113. Plaintiffs' reliance on the misrepresentations by Defendant was justified and reasonable in that such misrepresentations were made by individuals and entities that held themselves out as experts in the field of DNA testing, genetic sequencing, and biological research, and were in a position to know the true facts.

114. As a result of the negligent misrepresentations by Defendant, Plaintiff and Class members suffered the injuries and damages set forth above.

## Demand for Jury Trial

115. Plaintiffs demand a jury trial on all issues alleged above.

## Prayers for Relief

Wherefore Plaintiffs pray that judgment be entered against the Defendant for the following relief:

1. For an Order certifying that the Action may be maintained as a class action, certifying Plaintiffs as representatives of the Class, and designating their attorneys as Class counsel;
2. For equitable relief including a permanent injunction against Defendant from making any claims for the Device found to violate the law as set forth above, and requiring Defendant to make full restitution of all benefits it wrongfully obtained;
3. Costs of litigation and attorneys' fees;
4. Such other and further relief as the Court may deem just and proper.

Dated: December 20, 2013

ANKCORN LAW FIRM, PC

*/s/ Mark Ankcorn*

Attorneys for Plaintiffs
and the Proposed Class